

**Notice of Allowability**

Application No.

10/820,518

Examiner

Adam Marcetich

Applicant(s)

LEIBOFF, ARNOLD R.

Art Unit

3761

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09 July 2007.
2. ☒ The allowed claim(s) is/are 1-10 and 47-78.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other _____  |

## **DETAILED ACTION**

### **EXAMINER'S AMENDMENT / COMMENTS / REASONS FOR ALLOWANCE**

#### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Roffe on 11 September 2007. The application has been amended as follows:

2. Please cancel claims 11, 79, 80 and 81.

3. Please rewrite claims 1 and 59 as follows:

----- 1. A method for inserting an apparatus into a bowel, comprising:

inserting a guidewire into the bowel through an opening into the bowel; then  
passing a filament, unattached to the guidewire, from outside the bowel through the bowel wall into the bowel lumen and into initial engagement with the guidewire at a location in the bowel;

withdrawing the guidewire from the bowel through the opening into the bowel, after the filament is engaged with the guidewire, to thereby draw the filament through the bowel and out of the opening;

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attaching the apparatus to a portion of the filament after the guidewire and said portion of the filament have been withdrawn from the bowel; and

drawing the filament with attached apparatus back through the bowel, further comprising passing the filament back out the wall of the bowel, so that it penetrates the bowel wall in two locations, clamping a first end of the filament while a second end of the filament is free, the filament being engaged with the guidewire between the first and second ends such that as the guidewire is withdrawn from the bowel and out of the opening, the second end of the filament is drawn through the bowel and out of the opening, the apparatus being attached to the filament in the vicinity of the second end of the filament. -----

----- 59. A method for inserting an apparatus into a bowel, comprising:

inserting a forward end of a guidewire into the bowel through an opening into the bowel;

then passing the forward end of the guidewire to a second location in the bowel, then

without the forward end of the guidewire exiting the bowel, passing a filament through the bowel wall into the bowel lumen and then bringing the filament and forward end of the guidewire into engagement with one another at the second location in the bowel;

withdrawing the guidewire from the bowel through the opening into the bowel, after the filament is engaged with the guidewire, to thereby draw the filament through the bowel and out of the opening;

attaching the apparatus to the filament after the guidewire and a portion of the engaged filament have been withdrawn from the bowel;

drawing the filament with attached apparatus back through the opening in the bowel and through the bowel;

further comprising passing the filament back out the wall of the bowel, so that it penetrates the bowel wall in two locations, clamping a first end of the filament while a second end of the filament is free, the filament being engaged with the guidewire between the first and second ends such that as the guidewire is withdrawn from the bowel and out of the opening, the second end of the filament is drawn through the bowel and out of the opening, the apparatus being attached to the filament in the vicinity of the second end of the filament. -----

#### **ALLOWABLE CLAIMS**

4. Claims 1-10 and 47-78 are allowed over the prior art of record.

#### **REASONS FOR ALLOWANCE**

5. The following is an examiner's statement of reasons for allowance:
6. The closest prior art of record, Eld (US Patent 6,656,141) discloses the limitation of passing a filament through a bowel wall into a bowel lumen (column 2, lines 53-56). Similarly, Grant ["Percutaneous Endoscopic Gastrostomy"] discloses the limitation of passing a filament through a bowel wall into a bowel lumen (p. 170, paragraph 2, left column).

7. However, Eld and Grant each fail to teach or fairly suggest alone or in combination the essential steps of the claimed method, such as passing the filament back out the wall of the bowel, so that it penetrates the bowel wall in two locations. These steps are critical since two perforations are formed in the bowel. One end is allowed to pass freely through the bowel while the other is clamped in place.

8. The closest prior art of record, Gill (US Patent 5,851,195) discloses the limitation of attaching the apparatus to the filament (column 7, lines 5-21; Fig. 6, proximal end 30 of wire 28 attached to catheter tube 56 and Fig. 3, loop 32 on wire 28). However, Gill fails to teach or fairly suggest alone or in combination the essential steps of the claimed method, such as the step of attaching the apparatus to the filament comprising passing the filament through a tip of the apparatus and out a side hole thereof and then tying the filament to a filament button, and pulling on the filament so that the filament button returns to the interior of the apparatus and abuts against the inner surface of the tip of the apparatus, the filament button being dimensioned such that it is unable to pass back out through the tip of the apparatus thereby securing the filament to the apparatus. These steps, including the step of tying the filament to a filament button are critical since the claimed filament button provides a more secure attachment for a filament used to pull the apparatus through the bowel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ J. P. Grant. Percutaneous Endoscopic Gastrostomy. Initial placement by single endoscopic technique and long-term follow-up. Ann Surg. 1993 February; 217(2): 168–174.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich  
Examiner  
Art Unit 3761

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AMM

TATYANA ZALUKAEVA  
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